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C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA**

IN RE: Bard IVC Filters Products Liability
Litigation,

This Document Relates to:

Lisa Hyde, et al. v. C. R. Bard, Inc., et al.
CV-16-00893-PHX-DGC

No. 2:15-MD-02641-DGC

**DEFENDANTS' RESPONSE IN
OPPOSITION TO PLAINTIFFS'
MOTION *IN LIMINE* NO. 2 TO
EXCLUDE OR LIMIT
ARGUMENT AND EVIDENCE
REGARDING THE SURGEON
GENERAL'S CALL TO ACTION**

(Assigned to the Honorable David G.
Campbell)

Bard submits this response in opposition to Plaintiffs' Motion *in Limine* No. 2 and respectfully shows the Court as follows:

ARGUMENT AND CITATION OF AUTHORITY

I. The Surgeon General's Call to Action Is Admissible Under the Public Records Hearsay Exception.

Plaintiffs rely on *Philip Morris USA, Inc. v. Pollari*, 228 So. 3d 115 (Fla. Dist. Ct. App. 2017), a case applying the Florida Rules of Evidence, to argue this Court should hold the Surgeon General's Call to Action is inadmissible hearsay. But, Plaintiffs omit that the *Pollari* court explicitly found that, unlike the Florida Rules, the Surgeon General's reports at issue would be **admissible** under the Federal Rules:

The Surgeon General's Reports clearly fit only under that third category found in the Federal Rules as records relying on information supplied by outside sources and gathered during an investigation. The United States Court of Appeals for the Eighth Circuit in *Boerner v. Brown & Williamson Tobacco Co.*, 394 F.3d 594, 600 (8th Cir. 2005), reached that same conclusion when it affirmed a district court's admission of several Surgeon General Reports on smoking as public records falling under that third category. The Eighth Circuit concluded that even though the reports included factual findings "made by independent scientists and not on the basis of independent research by the Surgeon General," they were admissible because they were prepared by "a disinterested governmental agency" pursuant to a legal obligation "to report new and current information on smoking and health to the U.S. Congress." However, as [Florida precedent] instructs, **while such records may be admissible under the rules of the federal court system**, they are clearly inadmissible under the Florida Evidence Code."

Pollari, 228 So. 3d at 123 (emphasis added). Thus, this Court should find that under the Federal Rules, and consistent with its rulings in *Booker* and *Jones*, the Call to Action is a trustworthy public record.¹ See e.g., Surgeon General's Calls to Action, available at

¹ Plaintiffs also suggest that *Gruca v. Alpha Therapeutic Corp.*, 51 F.3d 638 (7th Cir. 1995) holds that the Call to Action should be excluded because it improperly suggests "that federal government's action 'absolved the defendants from liability for negligence.'" (Pl. Mot. at 3.) However, *Gruca* was based on the defense counsel's closing argument that the plaintiff "selected the defendants" and "could have sued the FDA." This was a "misstatement[] of law [because] the FDA is immune from suit." *Id.* at 645. The improper statement in *Gruca* does not remotely resemble Bard's use of the Call to Action.

1 <https://www.surgeongeneral.gov/library/calls/index.html> (last visited Aug. 23, 2018)
 2 (“Surgeon General Calls to Action are **science-based summary documents** intended to
 3 stimulate action nationwide to solve an urgent public health problem...Surgeon General’s
 4 advisories are **public statements**, on a public health issue, that provide evidence-based
 5 recommendations to the public.”) (emphasis added).

6 **II. The Surgeon General’s Call to Action is Relevant, Not Prejudicial, and Will**
 7 **Not Mislead the Jury.**

8 Plaintiffs’ complaints of prejudice echo their arguments rejected by the Court in
 9 admitting evidence of FDA’s 510(k) clearance process and the SIR Guidelines. Again,
 10 Plaintiffs seek to exclude evidence of a prominent public health entity recognizing IVC
 11 filters as an appropriate treatment option. But, Plaintiffs do not point to any legitimate
 12 prejudice from Bard’s limited use of the Call to Action. The record simply does not
 13 support Plaintiffs’ assertion that Bard argued at trial that it “acted at the direction of the
 14 Surgeon General” or that “the Surgeon General considers Bard’s IVC filters necessary ‘to
 15 treat [pulmonary embolism].” (Pl. Mot. at 2.) Rather, the Call to Action goes directly to
 16 the required risk-benefit analysis. As stated in Defendants’ Trial Brief, Wisconsin has
 17 adopted the risk-benefit test from the Restatement Third for strict product liability. Under
 18 that test, as well as the test for negligent design, what is reasonably foreseeable to the
 19 manufacturer and the community of users is a consideration. Wis. Stat. § 895.047(1) (“A
 20 product is defective in design if the *foreseeable* risks of harm posed by the product could
 21 have been reduced or avoided by the adoption of a reasonable alternative design...”);
 22 *Tesar v. Anderson*, 789 N.W.2d 351, 354 n.7 (Wis. App. 2010) (“[T]he concept of duty, as
 23 it relates to negligence cases, is inexorably interwoven with *foreseeability*.”) (emphasis
 24 added). The Call to Action, which includes references to 97 different pieces of medical
 25 literature collected by the Surgeon General’s office, and reflects the knowledge of health
 26 care providers and governmental public health entities at the time, goes directly to that
 27 analysis.
 28

Moreover, the Call to Action is one more piece of evidence to rebut Plaintiffs' claims that IVC filters, including Bard's filters, are not safe or effective. Indeed, Plaintiffs have designated Drs. Garcia and Streiff to specifically argue to the jury that anticoagulants are superior to IVC filters for the treatment of PE – **all** IVC filters, not just Bard's filters. Also, Plaintiffs' central themes include (1) that the FDA and medical community were unaware of the risks posed by Bard's IVC filters, and (2) that Bard's retrievable filters should have had the same safety profile of permanent filters such as the SNF. The Call to Action provides context to rebutting this assertion, in that the Surgeon General calls for the health care system to further "research the risks and benefits related to permanent versus retrievable placement of IVC filters." (Ex. A, at 31.) In other words, Plaintiffs ask this Court to allow them to present evidence to the jury that Bard, and only Bard, knew of risks associated with its IVC filters, yet deprive Bard from presenting evidence regarding widespread knowledge and acceptance of those risks in the medical community. It would be fundamentally unjust for Plaintiffs' request to be granted.

CONCLUSION

For these reasons, Bard respectfully requests that the Court deny Plaintiffs' Motion *in Limine* No. 2.

RESPECTFULLY SUBMITTED this 28th day of August, 2018.

s/ Richard B. North, Jr.

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CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of August 2018, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
Richard B. North, Jr.